

Clement J. Grassi, M.D.

Report in the matter of *In RE: Bard IVC Filters Products Liability Litigation*, Case Number MDL 15-02641-PHX DGC, in the United States District Court for the District of Arizona

PROFESSIONAL BACKGROUND

My name is Clement J. Grassi. I am a physician and interventional radiologist. The practice of interventional radiology involves the diagnosis, treatment and management of many disease conditions employing minimally invasive interventions and image-guided procedures. The procedures which I perform within the vascular system of the body include the use of catheters, guidewires, angioplasty balloons, stents, and implanted devices within the blood vessels, such as vena cava filters.

I am a graduate of Tufts University School of Medicine, and completed my post-graduate year one (PGY 1) at Massachusetts General Hospital as a surgical pathology resident, PGY 2 at Beth Israel /Deaconess Hospital, Boston, MA, in internal medicine, and completed my diagnostic radiology residency (3 years) also at the Beth Israel/Deaconess Hospital. I completed a two year fellowship in cardiovascular and interventional radiology at the Brigham and Women's Hospital which included training in all forms of catheterization (including cardiac catheterization), and experience in NIH-funded research.

On completion of my fellowship I was invited to continue as a radiology staff member at Brigham and Women's Hospital, Boston, MA, where I was employed for 15 years, and held an academic appointment at Harvard Medical School. I have also served as a staff radiologist at the Lahey Medical Center, Burlington, MA; the Boston VA Medical Center; the UMass Memorial Medical Center, Worcester, MA; and the New England Baptist Hospital, Boston, MA.

I am board certified by the American Board of Radiology in Diagnostic Radiology, and hold a Certificate of Added Qualifications in Vascular and Interventional Radiology. Within the Society of Interventional Radiology (SIR), an international medical society, I have been elected as a senior member, under the title of FSIR (Fellow of the Society of Interventional Radiology).

Additional details relating to my professional background and qualifications, including publications may be found on my attached curriculum vitae (CV). See Attachment A.

IVC FILTER BACKGROUND

I have first hand experience with the placement of vena cava filters which dates back to 1985 when I had the opportunity to place, in conjunction with Dr. David Levin, what is reportedly the first percutaneously placed femoral IVC filter at the Brigham and

Guidelines recommend removal of the filter. The FDA has recommended the same practice in its May 2014 Safety Communication. These practices are grounded not in routine imaging follow-up, nor in routine imaging of specific devices (e.g., Bard filters), but rather in individualized clinical assessment of patients' need for mechanical protection against PE.

Imaging of the filter does not inform the clinician about whether the need for mechanical filtration against PE has passed. Imaging should be undertaken only after an individualized clinical assessment of the patient is performed, and only if warranted after that assessment. Imaging also carries risks, including radiation exposure (e.g., CT scan or x-ray) or contrast-related issues or bleeding that can be associated with venograms.

Bard Filters

In my own experience, I have not encountered unexpectedly high complication rates with the Bard filter devices. At the 2017 Annual Scientific Meeting of the Society of Interventional Radiology, in which I participated, there was some discussion of the state of study of IVC filters and the general conclusion was that IVC filters are valuable tools in the treatment of patients with, or subject to, DVT and PE, and there was no new data presented showing the exact rate of complications with Bard, or any other manufacturers' IVC devices, and recognition that clinically significant complication associated with such filters, including fracture, tilt and penetration or perforation, can occur with any device, at low rates.

I have reviewed the Reports of the plaintiffs' medical experts. The Reports discuss in varying detail summaries and analysis of individual and collections of spontaneous adverse event reports, testing documents, Bard's internal e-mails and documents, and documents about product development. The Reports also discuss what a "reasonable physician" would want to know about a medical device. In my work with IVC filters and other medical devices, I have not received this type of information for any product. The documents and e-mails discussed in the Reports may be taken out of context or the data discussed may not allow for a scientifically reliable conclusion.

In treating patients with medical devices in my practice, I rely on the FDA's oversight of available products, the peer-reviewed medical literature, the product's instructions for use document, any other information from the manufacturer that has been properly analyzed and considered, my experience with the products, my colleagues' experiences with the products, and the patient's individual medical condition.

LIST OF TESTIMONY

See Attachment B.

LIST OF MATERIALS REVIEWED